

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

B21

-2- BASIC DOC.-

⑬



European Patent Office
Office européen des brevets

⑪ Publication number:

0 153 831
A3

⑫

EUROPEAN PATENT APPLICATION

⑰ Application number: 85300931.4

⑮ Int. Cl.: A 61 F 2/08, A 61 B 17/16

⑱ Date of filing: 13.02.85

⑲ Priority: 13.02.84 EP 84300875

④③ Date of publication of application: 04.09.85
Bulletin 85/36⑥② Designated Contracting States: AT BE CH DE FR GB IT LI
LU NL SE⑥④ Date of deferred publication of search
report: 09.09.87 Bulletin 87/37

⑦① Applicant: Seedhom, Bahaa Botros, 75 Holt Park
Crescent, Leeds 16 West Yorkshire (GB)
Applicant: Fujikawa, Kyosuke, Department of
Orthopaedic Surgery Kelo School of Medicine, Tokyo
(JP)

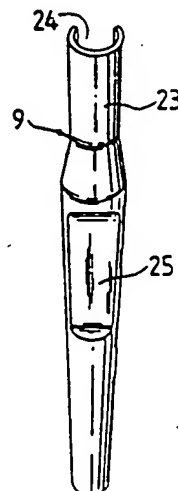
⑦② Inventor: Seedhom, Bahaa Botros, 75 Holt Park
Crescent, Leeds 16 West Yorkshire (GB)
Inventor: Fujikawa, Kyosuke, Department of
Orthopaedic Surgery Kelo School of Medicine, Tokyo
(JP)

⑦④ Representative: Harrison, Michael Robert et al,
URQUHART-DYKES & LORD 5th Floor Tower House
Merrion Way, Leeds LS2 8PA West Yorkshire (GB)

⑤④ Instruments for use in the surgical replacement of ligaments.

⑤⑦ This invention relates to a method and surgical instruments for use in the surgical replacement of a ligament and in particular for inserting a prosthetic ligament into the body.

The surgical instruments include a bone plug extractor (9) which is adapted to sever the base of the bone plug from a host bone to allow a complete separation of the bone plug. The instruments further include a clamp with a guide for locating the axis along which a bore is required for fixation of the ligament, a reamer cooperable with the clamp for removing an annulus of bone dust, and a cylindrical drill bit guide of the same outside diameter as the reamer and bone plug extractor.



EP 0 153 831 A3

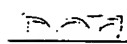
12

EUROPEAN PATENT APPLICATION

21 Application number: 85300931.4

51 Int. Cl.: A 61 F 2/08
 A 61 B 17/16

22 Date of filing: 13.02.85



30 Priority: 13.02.84 EP 84300875

43 Date of publication of application:
 04.09.85 Bulletin 85/36

84 Designated Contracting States:
 AT BE CH DE FR GB IT LI LU NL SE

71 Applicant: Seedhom, Bahaa Botros
 75 Holt Park Crescent
 Leeds 16 West Yorkshire(GB)

71 Applicant: Fujikawa, Kyosuke
 Department of Orthopaedic Surgery Keio School of
 Medicine
 Tokyo(JP)

72 Inventor: Seedhom, Bahaa Botros
 75 Holt Park Crescent
 Leeds 16 West Yorkshire(GB)

72 Inventor: Fujikawa, Kyosuke
 Department of Orthopaedic Surgery Keio School of
 Medicine
 Tokyo(JP)

74 Representative: Harrison, Michael Robert et al,
 URQUHART-DYKES & LORD 11th Floor Tower House
 Merriam Way
 Leeds LS2 8PB West Yorkshire(GB)

54 Instruments for use in the surgical replacement of ligaments.

57 This invention relates to a method and surgical instruments for use in the surgical replacement of a ligament and in particular for inserting a prosthetic ligament into the body.

The surgical instruments include a bone plug extractor which is adapted to sever the base of the bone plug from a host bone to allow a complete separation of the bone plug.

The instruments further include a clamp with a guide for locating the axis along which a bore is required for fixation of the ligament, a reamer cooperable with the clamp for removing an annulus of bone dust, and a cylindrical drill bit guide of the same outside diameter as the reamer and bone plug extractor.

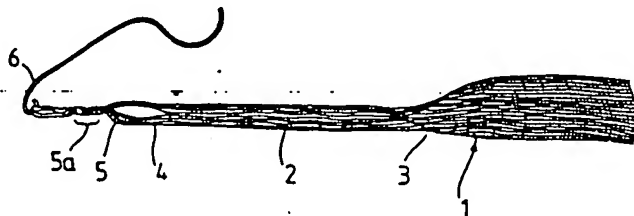


Fig.1.

- 1 -

INSTRUMENTS FOR USE
IN THE SURGICAL REPLACEMENT OF LIGAMENTS

This invention relates to surgical instruments
for use in the surgical replacement of a ligament
and in particular for implanting a prosthetic ligament
into the body.

The present invention is concerned with
a method of securing
a prosthetic ligament to a host bone comprising the steps
of:

removing a cylindrical bone plug from one surface of
the host bone to leave a cylindrical socket in the host
bone;

forming a bore of smaller diameter than the cylindri-
cal socket coaxial with the socket extending from the
cylindrical socket to an opposing surface of the host
bone;

drawing the prosthetic ligament through the
cylindrical socket and the bore;

replacing the bone plug into the socket thereby to
capture the prosthetic ligament between the bone plug and
the host bone.

The present invention is also concerned
with a method of
securing a prosthetic ligament to a first and second host
bone to extend between a first surface of the first host
bone and a second surface of the second host bone
comprising the steps of:

removing a first cylindrical bone plug from a third surface opposite to the first surface of the first host bone plug, to leave a first cylindrical socket;

5 forming a first bore of smaller diameter than the first socket, coaxial with the first socket and extending from the socket to the first surface of the first host bone;

removing a second cylindrical bone plug from a fourth surface opposite to the second surface of the second host bone to leave a second host socket;

10 forming a second bore of smaller diameter than the second socket coaxial with the second socket and extending from the socket to the second surface of the second host bone to form a shoulder between the socket and the bore;

providing a prosthetic ligament including at one end a pouch portion capable of receiving a cylindrical bone plug and including an opening
15 through which a bone plug may pass into the pouch portion;

passing the prosthetic ligament thorough the first socket, the first bore, the second bore and the second socket, whereby said pouch portion lies beyond said second socket;

inserting the second bore plug through the opening to lie within the
20 pouch portion;

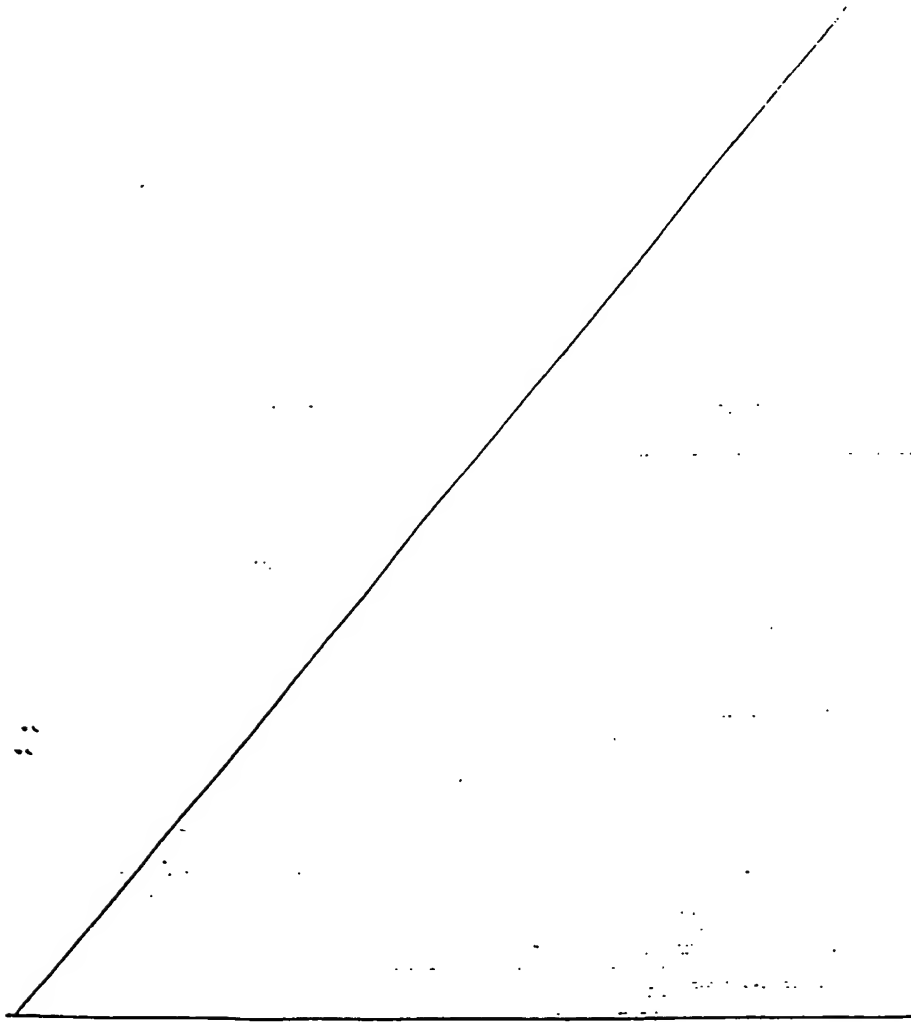
The present invention^{is} further^{concerned} with a technique for cutting and removing a replaceable bone plug from a host bone comprising:

25 forming an annular channel in the host bone to define the periphery of the plug;

applying a sharp blow to the plug along a direction transverse to the axis of the plug to sheat the plug from the host bone; and

30 removing the sheared plug from the host bone.
Preferably, before applying the sharp blow,

the plug is gripped by an instrument about an arcuate portion of its circumference and fully along its length, said arcuate portion being no greater than about 330° , and the sharp blow is applied to the instrument along a direction which is toward the ungripped portion of the plug.



In accordance with this invention there is provided a set of surgical instruments for use in the surgical replacement of an artificial ligament comprising a clamp with a guide for locating the axis along which a bore is required for fixation of a ligament, a reamer cooperable with the clamp for removing an annulus of bone dust, a bone plug extractor of the same outside diameter as the reamer, and a cylindrical drill bit guide of the same outside diameter as the reamer and bone plug extractor.

According to a further aspect of this invention a tool for guiding a cylindrical reaming tool along a predetermined axis to form a replaceable bone plug from a host bone comprises:

a first limb having a first pin at one end thereof, the pin being adapted to securely engage the bone;

a second limb having a guide for the reaming tool at one end thereof, said guide being oriented so that it will guide the reaming tool along a guiding axis which extends toward the first pin on the first limb;

at least two second pins adapted to securely engage the bone, the pins being mounted on the guide, said two second pins extending toward the first limb;

means for mounting the two second pins for adjustable rotational movement about the guiding axis of the guide to enable the second pins to be adjustably positioned to fit the contour of the bone;

means mounting the limbs for movement towards and away from each other and for applying a clamping force to the limbs whereby a bone may be engaged on opposite sides by said first pin and said second pins; and

means for preventing the two limbs of said clamp from swivelling relative to each other to cause misalignment of the guide pin of the first limb and the axis of the guide in the second limb.

Preferably the means for mounting the limbs for movement towards and away from each other comprises at least one screw threaded member and a handle to tighten the screw thread.

When the clamp has been placed on the bone, a reamer is inserted in
5 the cylindrical guide and is used to remove an annulus of bone dust from the bone. This locates the plug of bone to be removed and the clamp can now be removed. Occasionally the bone plug may break off and be retained within the reamer. Preferably the reamer includes a through hole into which a rod may be inserted to push the plug out of the reamer.

10 According to this invention a tool for extracting a cylindrical bone plug from a bone in which an annular channel has been formed to define the periphery of said bone plug, said tool being adapted to sever the base of said plug from the bone, the tool comprising:

a grippable handle portion at one end;

15 a wall portion at the other end, the wall portion defining a hollow, open-ended cylinder adapted to receive the bone plug;

a longitudinally extending slot formed in the cylindrical wall;

said wall being adapted to be received within said annular channel of said bone with the bone plug being receivable within the open-ended
20 cylinder, said slot defining an arcuate void region of the annular space in the bone.

The bone plug is extracted by inserting the cylindrical wall into the
annulus. A short, sharp blow is applied in the middle region of the
extractor while the handle is gripped, the force being applied at a point
25 in said middle region but on the side opposite to the slot. This severs the bone plug completely from the host bone.

Preferably the extractor includes a marker to indicate the correct area to be struck. More preferably this comprises a flattened bearing surface.

The bone plug extractor includes the grippable handle which must be gripped whilst the force is applied so that no bone damage occurs.

5 The bone plug extractor preferably includes means to aid turning the extractor about its longitudinal axis. For instance, the handle may include gripping means such as flutes or a knurled area. In addition the handle may include a hole or holes through which a torque bar may be introduced to extend transversely of the handle and by
10 means of which additional torque may be exerted should the friction between the extractor and the bone plug be too high to be overcome by merely gripping the handle.

When the bone plug has been removed a cylindrical drill bit guide is placed into the cylindrical socket formed in the bone. The drill bit guide
15 has a through hole for accommodating a drill bit which is introduced into the guide so that a reduced diameter bore is then drilled from the base of the cylinder to the other side of the bone at a region where the single pin of the clamp engages the bone. This region is selected to be as close as possible to the position where the original ligament was attached to
20 the bone.

This process is then repeated with the other bone to which the ligament is to be attached, the same instruments being used again.

Thus a set of tools according to this invention includes an above-mentioned clamp, a reamer which cooperates with this clamp, a bone plug
25 extractor of the same diameter as the annulus of the reamer, a rod which may be used with the bone plug extractor, and a cylindrical drill bit guide of the same diameter as the reamer and bone plug extractor.

A ligament of the type with which this invention is concerned may be used to replace

the cruciate ligaments of the knee. It can also, in the form of, for instance, a flat strip, be used to replace the medial ligament of the knee, or other ligaments or tendons of other joints.

A prosthetic ligament and a set of surgical instruments and a method
5 of inserting the ligament into the body will now be described by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of the prosthetic ligament;

Figure 2 is a perspective view of the set of surgical instruments used in the method;

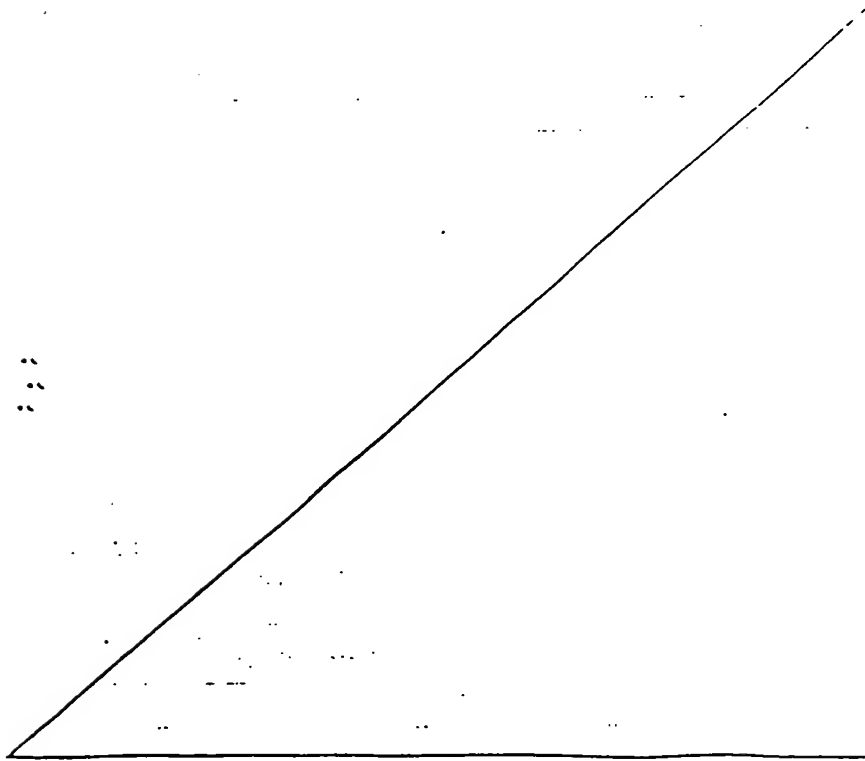


Figure 4 is a perspective view of the bone plug extractor;

Figure 4A is a view on that end of the bone plug extractor remote from the handle portion;

Figures 5 to 11 are representations (schematic only) of the steps of the method of replacing an anterior cruciate ligament in the knee.

An artificial ligament 1 comprises an elongate strip of open weave polyester. This fabric is Terylene and is a mock leno weave comprising a warp of 550 Decitex polyester yarn and a weft of twisted polyester yarn. The holes are 0.1 x 0.2 cm. There are fourteen to fifteen holes across the width of the strip, and twenty holes per cm².

The ligament is in the form of a tube 2 which has a slit 3 at one open end of the ligament 1 which extends to the open end edge of the ligament and a slit 4 at the other closed end of the ligament. The end of the slit 4 remote from the centre of the tube 2 is closed by a row or more of stitching or by dense weaving or in some other manner, to form a pouch capable of receiving a bone plug. As far as at the end of this row of stitching or densely woven section, the ligament extends further by a short portion 5a of the same open weave as the central portion 2. A threading cord 6 is attached to a position on this shorter portion 5a from the closure portion. The purpose of threading cord 6 is to allow the ligament to be pulled through the bores in the bone.

A bone plug may be inserted into the pouch through the slit 4. The stitching or densely woven section 5 forms a closure which prevents movement of the bone plug out of the pouch in a direction away from the centre of the ligament 1.

In order to illustrate the slit 4, the ligament 1 has been shown in Figure 1 with a light coloured tubular insert. This means that the pouch-like structure is not clearly illustrated.

A set of surgical instruments for use in the implantation of the ligament comprises a clamp 7, a reamer 8, a bone plug extractor 9, a push rod 10 and a drill bit guide 12.

Clamp 7 comprises two parallel limbs 13 and 14 interconnected by a main spacer rod 15 and an auxiliary rod 16. Main spacer rod 15, approximately centrally located in the clamp, is threaded from one end portion to a position lying about one third to one half of the length of the rod from that end portion. The threaded portion is in threaded engagement with a threaded bore located in limb 13 at the appropriate distances from the ends. The remainder of rod 15 is unthreaded and extends from the threaded portion through limb 14 to terminate in an enlarged head portion 17 carrying a handle 17a. For much of its length, this unthreaded portion of rod lies within a sleeve 16a which extends through limb 14 to which it is fixed. Within limb 14 sleeve 16a defines the bore through which rod 15 extends.

Auxiliary rod 16 is fixed at one end to limb 14 and extends through a bore or a slot in the other limb 13 for sliding movement therewithin.

The limb 14 includes a guide pin 18 extending perpendicularly from that end of the limb 14 remote from auxiliary rod 16. In use guide pin 18 engages the bone to locate the position of attachment of the ligament to the bone.

The other limb 13 has mounted on it a cylindrical guide 19 which is rotatably mounted within a bore in limb 13 and is provided with a circlip 19a to prevent movement of the guide out of its bore in limb 13. The other end of cylindrical guide 13 is in the form of an enlarged section or pin support 20a which in turn carries two pins 20. Extending through cylindrical guide 19 is a bore for receiving the reamer 8 such that reamer

8 will extend in a direction towards guide pin 18. The axes of guide pin 18 and said cylindrical guide are collinear.

As best seen in Figure 3, pins 20 are mounted on support 20a in a position offset from the bore extending through the guide 20 and at an angle to the axis of this bore. Guide 19 may be rotated within limb 13 so that the pins 20 describe the circumferential movement about the centre of the bore extending through guide 19. The position and orientation of the pins on guide 19 take account of the different contours of bone with which the clamp 7 may be used.

The reamer 8 passes through the cylindrical guide 19 and has sharp cutting edges 21, which are milled along its surfaces and form sharp teeth at the rim of the reamer, and a handle 22 which may be used to oscillate the cutting edges 21 to remove the bone dust.

The bone plug extractor 9 includes at one end a cylindrical wall 23 which defines an open ended cylinder. At its other end the tool 9 includes a grippable handle 23a.

Extending from the edge of the wall 23 is a slot 24 which defines an arcuate void in the cylindrical wall of the same length as that of section 23. The angle circumscribed by the slot is about 80°. As shown in Figure 4A, this angle c is subtended between the ends a, b of the slot and the centre of the circular portion of the wall 23.

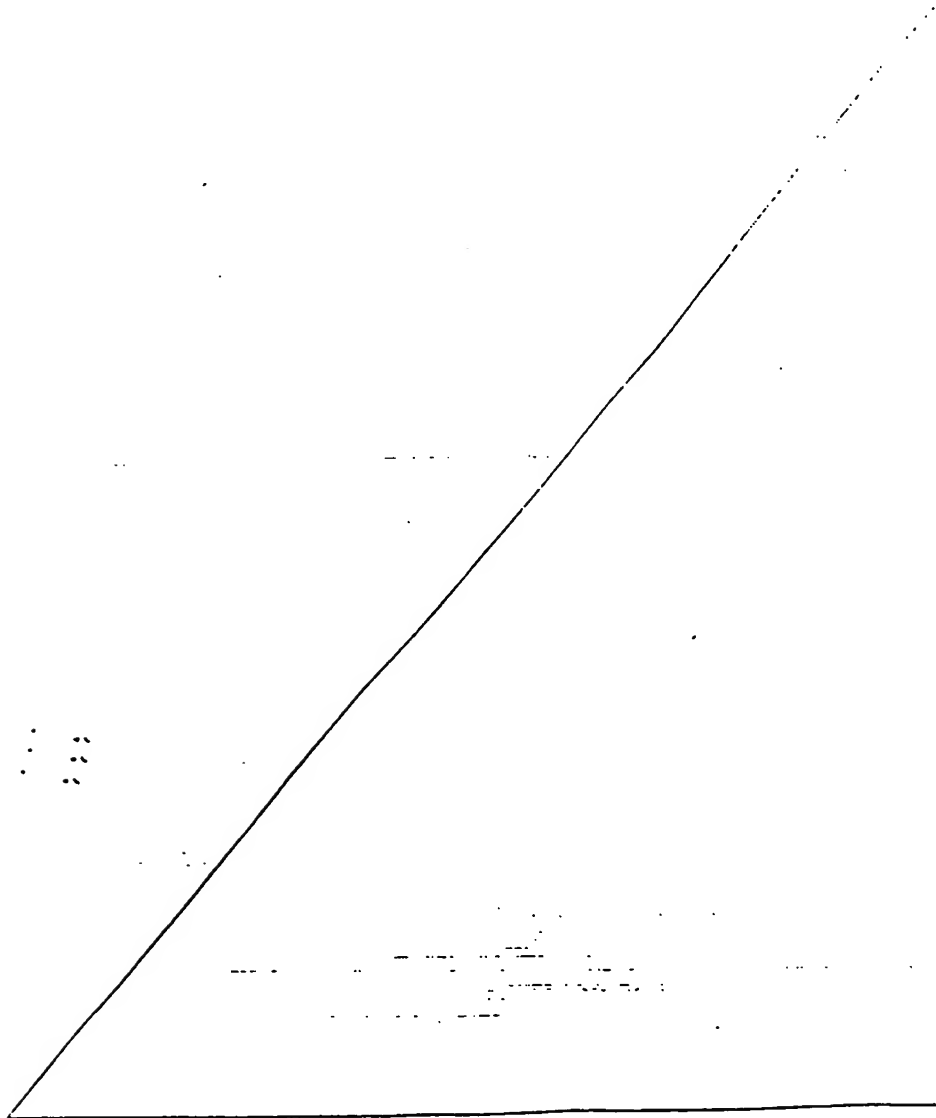
On the opposite side of the bone plug extractor 9 to the slot 24 is a flattened bearing surface 25. This defines an area to be struck in order to sever a base of a bone plug being removed by the extractor tool 9.

The drill bit guide 12 is placed in the cylindrical hole created in the bone and is used as a guide for the drill bit to drill out the reduced diameter portion of the bore.

CLAIMS:

1. A tool for extracting a cylindrical bone plug from a bone in which an annular channel has been formed to define the periphery of said bone plug, said tool being adapted to sever the base of said plug from the bone to enable complete separation of the plug from the bone, the tool comprising:
 - a grippable handle portion at one end;
 - a wall portion at the other end, the wall portion defining a hollow, open-ended cylinder adapted to receive the bone plug;
 - a longitudinally extending slot formed in the cylindrical wall;
 - said wall being adapted to be received within said annular channel of said bone with the bone plug being receivable within the open-ended cylinder, said slot defining an arcuate void region of the annular space in the bone.
2. A bone plug extractor tool as defined in claim 1, wherein the angle circumscribed by said slot is between about 30° and less than 180° .
3. A bone plug extractor tool as defined in claim 1, wherein the angle circumscribed by said slot is from about 70° to about 90° .
4. A bone plug extractor tool as defined in claims 1 to 3, further comprising:
 - indicia means on the tool indicating that region of the tool which is diametrically opposed to the longitudinal slot.
5. A bone plug extractor tool as defined in claim 4, wherein the indicia comprises a flattened bearing surface, said flattened bearing surface defining a strikable surface.
6. A set of tools for use in the surgical replacement of prosthetic ligaments comprising a clamp with a guide for locating the axis along which a bore is

required for fixation of a ligament, a reamer cooperable with the clamp for removing an annulus of bone dust, a bone plug extractor in accordance with claim 1, of the same outside diameter as the reamer, and a cylindrical drill bit guide of the same outside diameter as the reamer and bone plug extractor.



7. An orthopaedic tool for guiding a cylindrical reaming tool along a predetermined axis to form a replaceable bone plug from a host bone comprising:

5 a first limb having a first pin at one end thereof, the pin being adapted to securely engage the bone;

a second limb having a guide for the reaming tool at one end thereof, said guide being oriented so that it will guide the reaming tool along a guiding axis which extends toward the first pin on the first limb;

10 at least two second pins adapted to securely engage the bone, the pins being mounted on the guide, said two second pins extending toward the first limb;

means mounting the two second pins for adjustable rotational movement about the guiding axis of the guide to enable the second pins to be adjustably positioned to fit the contour of the bone;

15 means mounting the limbs for movement towards and away from each other and for applying a clamping force to the limbs whereby a bone may be engaged on opposite sides by said first pin and said second pins; and

means for preventing the two limbs of said clamp from swivelling relative to each other to cause misalignment of the guide pin of the first 20 limb and the axis of the guide in the second limb.

8. A method of securing a prosthetic ligament to a host bone comprising the steps of:

removing a cylindrical bone plug from one surface of the host bone to leave a cylindrical socket in the host bone;

25 forming a bore of smaller diameter than the cylindrical socket coaxial with the socket extending from the cylindrical socket to an opposing surface of the host bone;

drawing the prosthetic ligament through the cylindrical socket and the bore;

replacing the bone plug into the socket thereby to capture the prosthetic ligament between the bone plug and the host bone.

5 9. A method of securing a prosthetic ligament to a first and second host bone to extend between a first surface of the first host bone and a second surface of the second host bone comprising the steps of:

removing a first cylindrical bone plug from a third surface opposite to the first surface of the first host bone plug, to leave a first cylindrical
10 socket;

forming a first bore of smaller diameter than the first socket, coaxial with the first socket and extending from the socket to the first surface of the first host bone;

removing a second cylindrical bone plug from a fourth surface opposite
15 to the second surface of the second host bone to leave a second host socket;

forming a second bore of smaller diameter than the second socket coaxial with the second socket and extending from the socket to the second surface of the second host bone to form a shoulder between the socket and the bore;

20 providing a prosthetic ligament including at one end a pouch portion capable of receiving a cylindrical bone plug and including an opening through which a bone plug may pass into the pouch portion;

passing the prosthetic ligament through the first socket, the first bore, the second bore and the second socket, whereby said pouch portion lies
25 beyond said second socket;

inserting the second bore plug through the opening to lie within the pouch portion;

preventing the second bone plug from escaping from the pouch opening in a direction towards the fourth surface of the second host bone;

pulling the prosthetic ligament in a direction towards the second surface of the second host bone to force the second bone plug against the shoulder
5 between the socket and the bore to secure the prosthetic ligament to the second host bone;

replacing the first bone plug into the first socket thereby to capture the prosthetic ligament between the host bone and the first bone plug whereby the ligament is secured to the first and second host bones.

10 10. A technique for cutting and removing a replaceable bone plug from a host bone comprising:

forming an annular channel in the host bone to define the periphery of the plug;

15 applying a sharp blow to the plug along a direction transverse to the axis of the plug to shear the plug from the host bone; and

removing the sheared plug from the host bone.

11. A technique as defined in claim 10 further comprising:

before applying the sharp blow, gripping the plug by an instrument about an arcuate portion of its circumference and fully along its length,
20 said arcuate portion being no greater than about 330°, and applying said sharp blow to the instrument along a direction which is toward the ungripped portion of the plug.

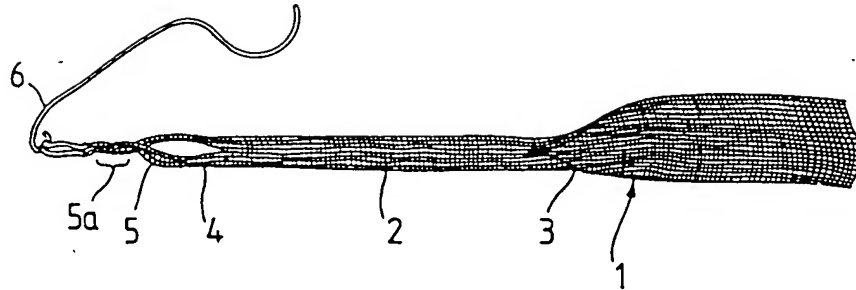


Fig. 1.

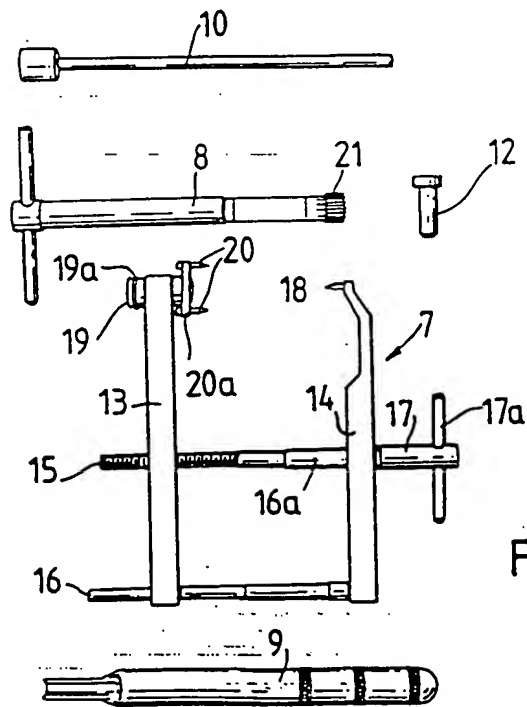


Fig. 2.

0153831

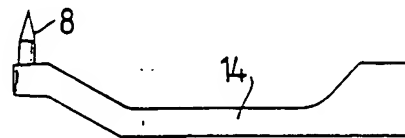
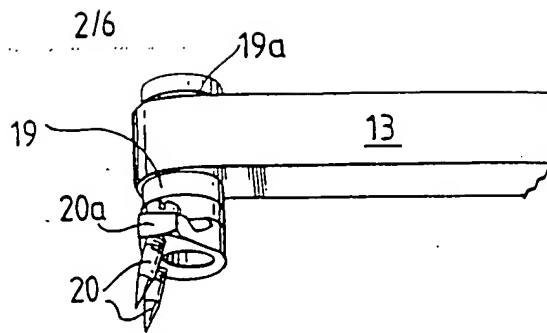


Fig.3.

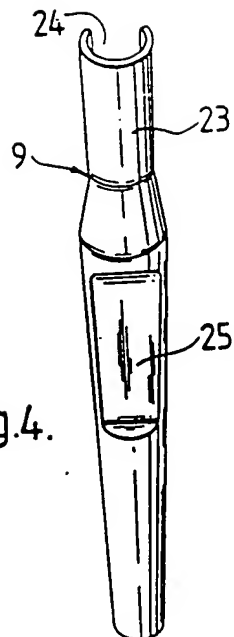


Fig.4.

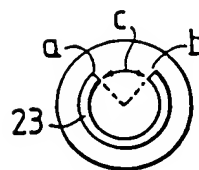
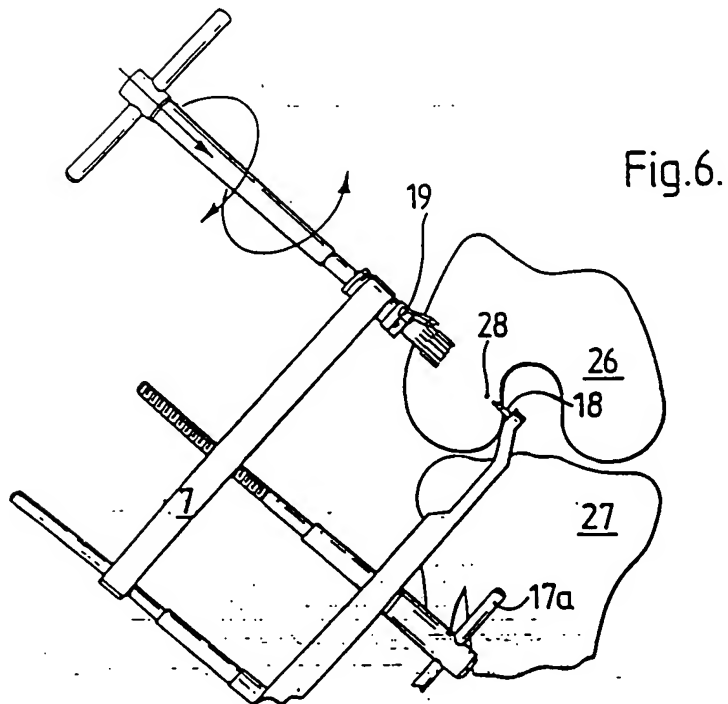
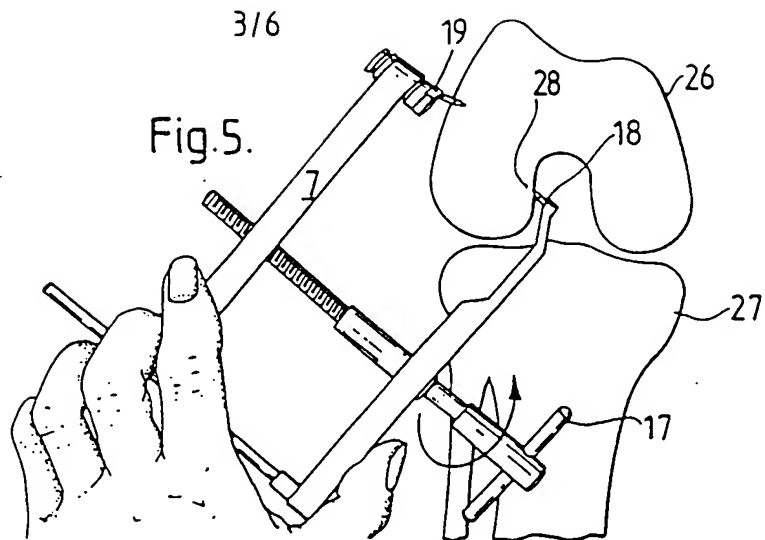


Fig4A.



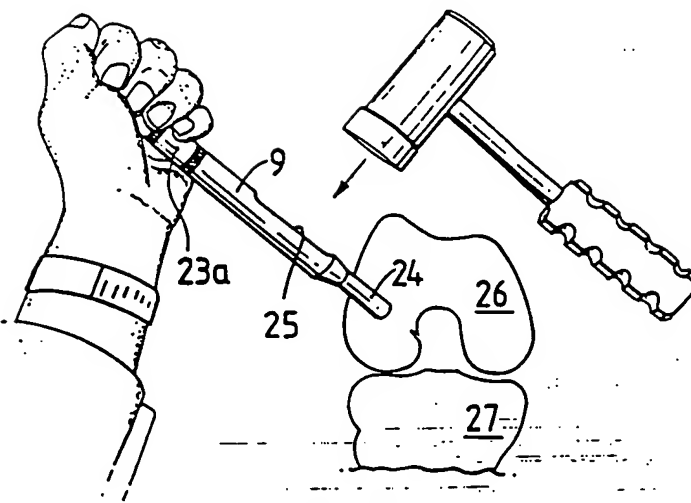
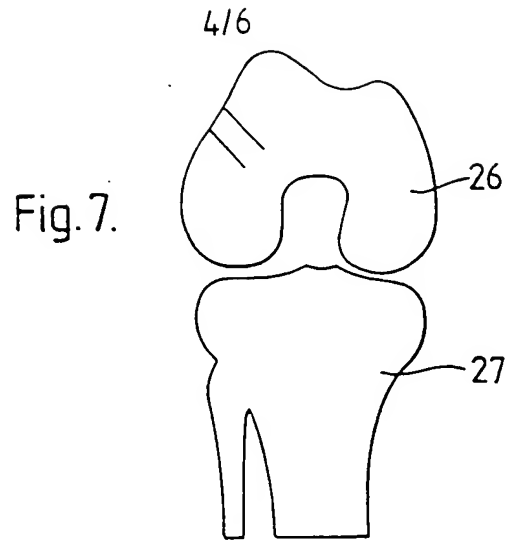
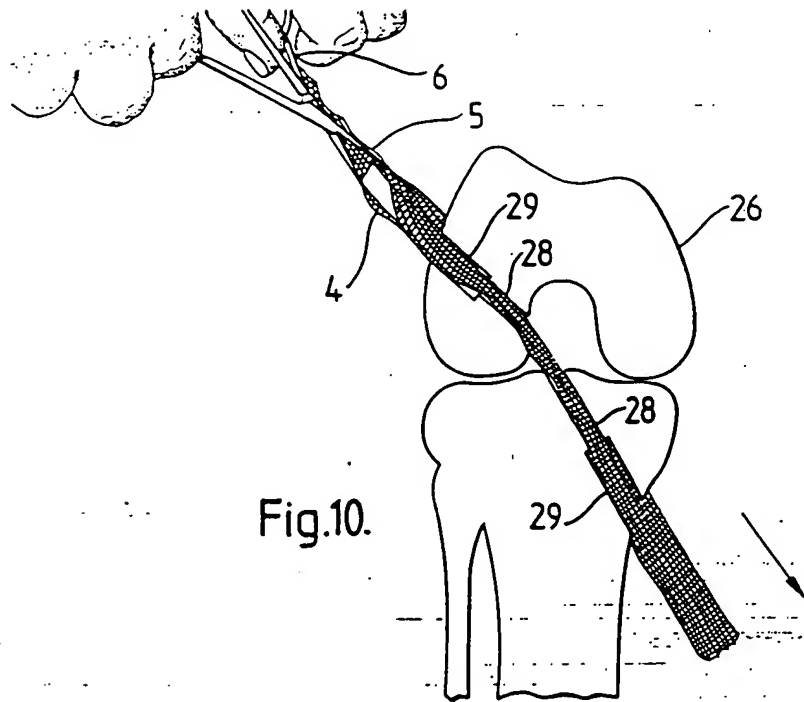
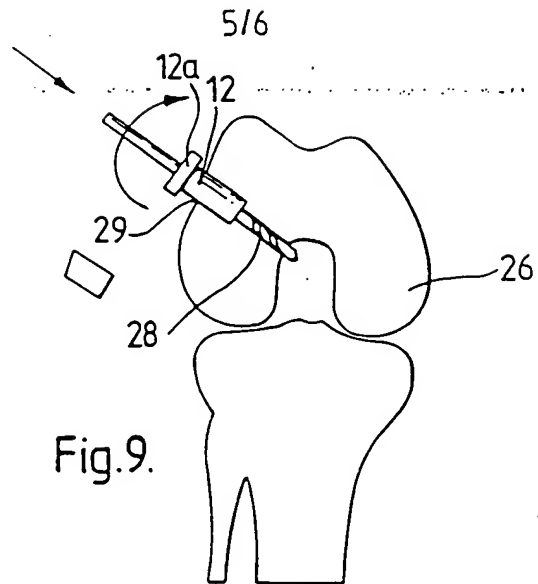


Fig. 8.



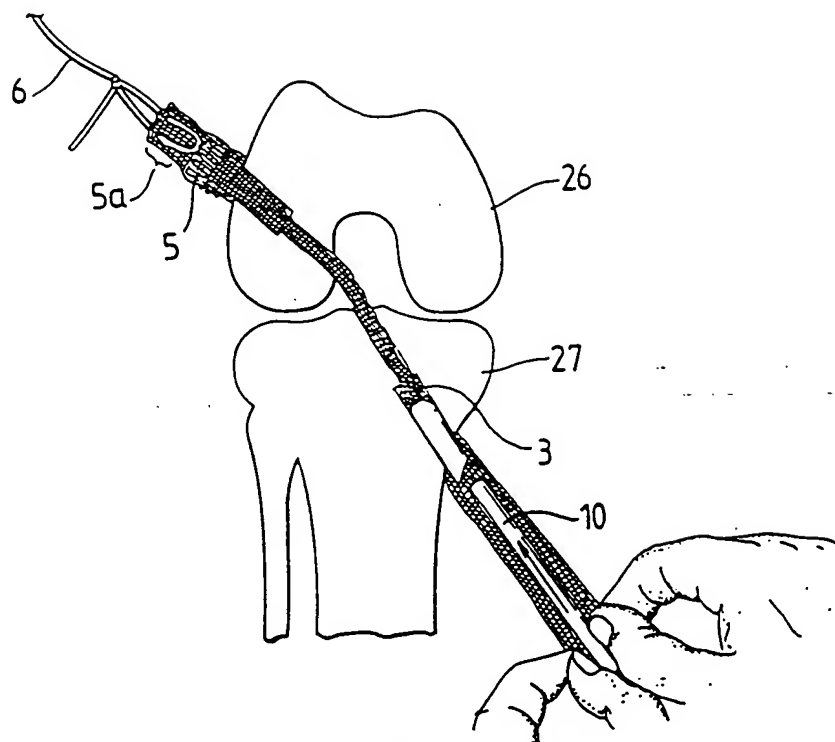


Fig.11.



European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT
which under Rule 45 of the European Patent Convention
shall be considered, for the purposes of subsequent
proceedings, as the European search report

0153831

Application number

EP 85 30 0931

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
Y	US-A-3 913 566 (LACEY) * Figures; column 2, line 34 - column 5, line 15 * ---	1,2	A 61 F 2/08 A 61 B 17/16
Y	US-A-4 059 115 (JUMASHEV) * Abstract; figures * ---	1,2	
A	US-A-4 096 749 (STEWART) * Figure 4 * ---	1	
A	BE-A- 531 833 (CLEMENT) * Figures; page 2, line 39 - page 3, line 54 * ---	3	
L,P, X	EP-A-0 126 520 (SEEDHOM) * Whole document * -----	1,7	
			TECHNICAL FIELDS SEARCHED (Int. Cl.4)
			A 61 B
			A 61 F
			B 23 B
			G 01 N
INCOMPLETE SEARCH			
<p>The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims.</p> <p>Claims searched completely: 1-7 Claims searched incompletely: 8-11 Claims not searched: 8-11 Reason for the limitation of the search:</p> <p>Method for treatment of the human or animal body by surgery or therapy (see art. 52(4) of the European Patent Convention).</p>			
Place of search The Hague		Date of completion of the search 22-06-1987	Examiner STEENBAKKER
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons 3 : member of the same patent family, corresponding document	